



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,677	02/05/2001	Jan Otto Solem	JM-050 CIP	3473

7590

10/21/2003

CHRIS JAMES
EDWARDS LIFESCIENCES LLC
ONE EDWARDS WAY
IRVINE, CA 92614

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 10/21/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 22, 24-27, 29-40, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 24-27, 29, 31-36, 73 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 is/are allowed.
- 6) ☒ Claim(s) 22, 30 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3738

DETAILED ACTION

Response to Amendment

1. The amendment filed 5/30/03 has been entered as Paper No. 24. Changes to the specification have been approved by the examiner, and claims 21, 23 and 28 have been canceled. Applicant should note that in the listing of claims, claims 18-20 and 41-72 are indicated as "withdrawn". However, these claims were canceled in the amendment filed 8/6/02.
2. The claims currently pending are 1-17, 22, 24-27, 29-40, 73 and 74, of which claims 1-13, 24-27, 29, 31-36, 73 and 74 are withdrawn from consideration for being directed to a non-elected species. The claims being considered for further examination on the merits are 14-17, 22, 30 and 37-40.

Election/Restrictions

3. Claims 22 and 40 are generic. Upon their allowance, the claims dependent thereon that were withdrawn from consideration for being directed to non-elected species would no longer be withdrawn. These dependent claims will be allowed only if they are fully supported by the original specification. Claims 24, 29 and 31 would not be allowed because they contain new matter.

Interference

4. Claim 22 this application is asserted by applicant to correspond to claim(s) of U.S. Application No. 09/494,233, now U.S. Patent No. 6,402,781 and of U.S. Application No. 09/909,193.

Art Unit: 3738

5. The examiner does not consider claim 22 to be directed to the same invention as that of U.S. Patent No. 6,402,781 because claim 1 of the '781 patent requires a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration, and a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus. Claim 15 of the '781 patent requires a forming element attached to the elongate body, wherein the forming element is adapted to be severed. Claim 22 of the current application claims neither the forming element nor the lock. Therefore, applicant's claimed invention of claim 22 is patentably distinct from claims 1, 15 and all other independent claims of the '781 patent. Accordingly, an interference cannot be initiated based upon this claim.

6. The examiner does not consider claim 22 to be directed to the same invention as that of U.S. Application No. 09/909,163 because claim 1 of the '163 application requires a method of treating congestive heart failure wherein an implant is positioned in the coronary sinus and is formed into a loop. Accordingly, an interference cannot be initiated based upon this claim.

7. Applicant argues that the concept of "a lock and forming element adapted to be severed" is indeed disclosed in the specification in Figure 13. Applicant asserts that the wires 26, 27 are secured (i.e. locked) to the adjacent stent sections after the distances between the sections have been reduced, and the ends of the wires are severed. The examiner disagrees. While the wires are secured in some fashion to the stent sections, they are not secured to the sections *after* distances have been reduced. Furthermore, the figure and written disclosure are silent to a "lock", a structure that retains the body in the second configuration. The wires simply reduce the distances between the stent sections, and do not provide "a lock" at the point they are secured to

Art Unit: 3738

the stent sections for retaining the body in the second configuration. In addition, the figure and written disclosure are completely silent to the wires being severed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 38 and 39 are indefinite because it is unclear how they further limit the claimed invention of a medical device for remodeling an extravascular tissue structure adjacent to a vessel in a patient. The deployment system is not a structural element of the medical device itself, but rather is used to deliver the medical device into the coronary sinus. Is applicant attempting to claim a combination of the medical device and deployment system? If so, applicant should keep in mind that the restriction requirement limits the examination on the merits of an invention to only the device.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3738

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 22, 30, 37 and 40 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,210,432.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim an elongate body adapted to be positioned in the coronary sinus and remodel the mitral valve annulus by reducing the circumference thereof when the elongate body is adjusted to a second configuration.

Allowable Subject Matter

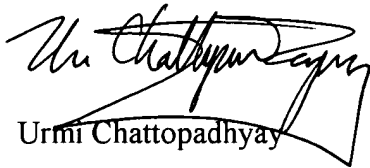
12. Claims 14-17 are allowed.

13. Claims 38 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am - 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738

October 9, 2003



David J. Teabella
Patent Examiner